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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,035	11/19/2001	Joseph Emmerich	P07374US00/LRP	5320

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EXAMINER	
FIELD, TAMMY K	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,035	EMMERICH ET AL.	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Election/Restrictions

1. This Office action is responsive to the Applicant's election in the Official response received December 8, 2003 and to added new method claims 7-11 received in the Office November 4, 2003.

Applicant's election of Group I (Claims 1 and 2) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted Claims 7-11, drawn to a method of treating venous thromboembolic disease, wherein an effective amount of an agent active on bacteria of the *Chlamydia* genus with a carrier is administered are different than those of Group I, drawn to a method for determining whether an individual has been infected with the *Chlamydia* genus.

The Office maintains that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature of claim 1, a method for determining, whether an individual has been infected with the *Chlamydia* genus due to the art of Gencay M. *et al.* (Eur. J. Epidemiol. Published July 1998) who teach a method of detecting *Chlamydia pneumonia* with serological markers using a microimmunofluorescence test for patients at page 506-507. Therefore, Unity of Invention is not fulfilled because there is not a technical feature that is "special", in that the technical feature does not define a contribution over the art. As such, a method for determining, whether an individual has been infected with the *Chlamydia* genus lacks unity of invention with the methods of use set forth in Inventions I. Invention II does not require

the use of the technical feature of Group I and since they define a separate technical feature as set fort supra, Inventions I and II lack unity of invention because they do not form a single general concept. Furthermore, the different technical feature of Invention II does not rely upon the technical feature of Invention I and therefore also lack unity of invention because they lack a technical feature in common within the meaning of PCT Rule 13.2.

The restriction requirement by determining Lack of Unity is deemed proper and is therefore made **FINAL**.

2. New Claims 7-11 are withdrawn from consideration as drawn to the non-elected Invention of Group II.

3. Claims 1 and 2 are presently under examination.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

In regard to applicant's claim for foreign priority based on the French application, 99 03612 filed on March 23, 1999, it is noted that the Office has not received a certified copy of the translation of this application as required by 35 U.S.C. 119(b).

Specification

5. The disclosure is objected to because of the following informalities:

a. Page 14 – Table 2, Typo in heading of IgG "tit rs", should read "titers"

b. Page 15 – Table 3, Typo in Title "function of th " should read "function of the"

Appropriate correction is required.

6. The trademarks for SAS and applicable trademark pertaining to SAS are missing in this application specifically at page 9, line 10. It should be capitalized wherever it appears and be accompanied by the correct generic terminology. Additionally, the parenthesis at Page 9, line11 should read (SAS Institute Inc., Cary, N.C.).

The use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

7. The listing of references at page 16 in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

8. Claim 2 objected to because of the following informality:

a. Remove the word "of" in "...sample <u>of</u> from said individual."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* detection of *Chlamydia pneumoniae* IgG antibodies and the association between the serological status for C. pneumoniae and venous thrombosis, does not reasonably provide enablement for *in vitro* predisposition to a venous thromboembolic disease in an individual. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims encompass a method of determining, *in vitro*, predisposition to a venous thromboembolic disease in an individual, in which it is determined whether the individual has been infected by a *Chlamydia pneumoniae* by assaying the level of anti-Chlamydia antibodies in a biological sample from said individual.

The teachings of the specification are limited to identifying an association between the circulating titers of anti-*C. pneumoniae* IgG antibodies and the presence of individuals less than 61 years old with venous thromboembolic diseases and/or who individuals who exhibited the Arg 506 Gln mutation in coagulation Factor V.

The teachings of the specification do not disclose how the of association of circulating titers of anti-*C. pneumoniae* IgG antibodies indicate a predisposition to a venous thromboembolic disease in an individual. The specification is also silent in regard to

predisposition of thromboembolic disease in the presence of *C. pneumoniae* infection and the causal Arg 506 Gln mutation in coagulation Factor V linked with a thromboembolic disease.

Maraha, B. *et al.* 2002. (Diag. Micro. Infect. Dis. 42:153-157) teach that there exists controversial reports on the association between venous thrombosis and the serology of *C. pneumoniae* at page 153, paragraph 3. Maraha, B. *et al.* Further investigated, in a case controlled study of 532 subjects, whether C. *pneumoniae* is associated with an increased risk for venous thrombosis using C. *pneumoniae* IgG serology and IL-6 and IL-8 levels compared to control subjects at page 155, Paragraph 6 - page 155 (see Fig. 2). Maraha, B. *et al.* Concluded from results obtained that C. *pneumoniae* as detected by serology or through molecular testing by PCR of peripheral blood cells is not associated with increased risk of venous thrombosis at page 155, paragraph 2 and at page 157, paragraph 1.

The art of Lozinguez, O. *et al.* 2000. (Thromb. Haemost. 83:887-891) teach that although there is clearly a link between *C. Pneumoniae* serological status and venous thrombosis at results, page 888-889, the serological link between *C. Pneumoniae* and venous thromboembolism does not establish a causal relation, as it fails to show whether *C. pneumoniae* infection precedes the disease or whether the microorganism is present within the vessel wall at page 890, paragraph 6.

In view of the state of the prior art set forth supra, the nature of the invention, and the predictability or lack thereof in the art, it is determined upon further consideration of the instant disclosure and weighing all evidence in the record that the specification is not enabling. In conclusion, it is also determined that undue experimentation would be needed to use the claimed invention.

Therefore, for purposes of examination the claims are interpreted to read on a method of determining, *in vitro*, whether an individual has been infected by a *Chlamydia pneumoniae* by assaying the level of anti-Chlamydia antibodies in a biological sample from said individual.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ong, G. *et al.* 1996. (J. Clin. Pathol. 49: 102-106).

The claims are drawn to a method of determining, *in vitro*, whether an individual has been infected by a *Chlamydia pneumoniae* by assaying the level of anti-Chlamydia antibodies in a biological sample from said individual.

Ong, G. *et al.* teach a method of determining, *in vitro*, whether an individual has been infected by a *Chlamydia pneumoniae* by an assay using an indirect immunofluorescence technique for determining the level of anti-Chlamydia antibodies in a biological tissue sample from an individual at page 103, paragraph 2.

Thus, Ong, G. *et al.* anticipates the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the methods of the prior art (*i.e.* that the

methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205 USPQ 594.

Status of the Claims

11. No claims are allowed.

Conclusion

12. The prior art of record and not relied upon is considered pertinent to applicant's disclosure:

a. Fryert, R.H. *et al.* 1997. Chlamydia species infect human vascular endothelial cells and induce procoagulant activity. J. Investigative Medicine 45(4): 168-174.

b. Emmerich, J. 2002. Infection and venous thrombosis. Pathophysiol. Haemost Thromb. 2002. 32(5-6): 346-348.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the

organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TKF

Tammy K. Field
December 17, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600